Complete Summary

GUIDELINE TITLE

Meningitis.

BIBLIOGRAPHIC SOURCE(S)

Meningitis. Philadelphia (PA): Intracorp; 2005. Various p. [16 references]

GUIDELINE STATUS

This is the current release of the guideline.

All Intracorp guidelines are reviewed annually and updated as necessary, but no less frequently than every 2 years. This guideline is effective from July 1, 2005 to July 1, 2007.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

On October 3, 2005, The U.S. Food and Drug Administration (FDA) and CDC notified consumers and health care providers of five reports of Guillain Barre Syndrome following administration of Meningococcal Conjugate Vaccine A, C, Y, and W135 (trade name Menactra), manufactured by Sanofi Pasteur. It is not known yet whether these cases were caused by the vaccine or are coincidental. FDA and CDC are sharing this information with the public now and actively investigating the situation because of its potentially serious nature. Guillain Barre Syndrome (GBS) is a serious neurological disorder that can occur, often in healthy individuals, either spontaneously or after certain infections. GBS typically causes increasing weakness in the legs and arms that can be severe and require hospitalization. Because of the potentially serious nature of this matter, FDA and CDC are asking any persons with knowledge of any possible cases of GBS occurring after Menactra to report them to the <u>Vaccine Adverse Event Reporting System (VAERS)</u> to help the agencies further evaluate the matter. See the <u>FDA Web site</u> for more information.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Meningitis, including

- Bacterial meningitis
- Viral, or aseptic, meningitis
- Fungal meningitis

GUIDELINE CATEGORY

Diagnosis Evaluation Management Prevention Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Neurology
Pediatrics
Preventive Medicine

INTENDED USERS

Allied Health Personnel Health Care Providers Health Plans Hospitals Managed Care Organizations Utilization Management

GUIDELINE OBJECTIVE(S)

To present recommendations for the diagnosis, treatment, prevention, and management of meningitis that will assist medical management leaders to make appropriate benefit coverage determinations

TARGET POPULATION

Individuals with suspected or known meningitis

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

- 1. Physical examination and assessment of signs and symptoms
- 2. Diagnostic tests:
 - Computerized tomography (CT) scan
 - Lumbar puncture
 - Laboratory tests, including
 - Blood cultures
 - White blood cell (WBC) count
 - Blood urea nitrogen (BUN) and creatinine
 - Cerebral spinal fluid (CSF) leukocytes, neutrophils, lymphocytes, glucose, protein, gram stains

Management/Treatment/Prevention

Bacterial Meningitis

- 1. Endotracheal intubation if required
- 2. Intravenous antibiotics
- 3. Dexamethasone if needed
- 4. Intravenous hydration
- 5. Analgesics

Viral Meningitis

- 1. Symptomatic relief (fluids, bed rest, analgesics, sedatives)
- 2. Antibiotics if there is suspicion for bacterial meningitis
- 3. Acyclovir in some cases

Prevention

Meningococcal polysaccharide conjugate vaccine (Menactra)

MAJOR OUTCOMES CONSIDERED

- Risk factors and prognosis
- Utility of diagnostic tests
- Clinical outcomes and risk reduction associated with treatment:
 - Morbidity and mortality
 - Length of illness

METHODOLOGY

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were performed of the following resources: reviews by independent medical technology assessment vendors (such as the Cochrane Library, HAYES); PubMed; MD Consult; the Centers for Disease Control and Prevention (CDC); the U.S. Food and Drug Administration (FDA); professional society position statements and recommended guidelines; peer reviewed medical and technology publications and journals; medical journals by specialty; National Library of Medicine; Agency for Healthcare Research and Quality; Centers for Medicare and Medicaid Services; and Federal and State Jurisdictional mandates.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE FVI DENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A draft Clinical Resource Tool (CRT or guideline) is prepared by a primary researcher and presented to the Medical Technology Assessment Committee or the Intracorp Guideline Quality Committee, dependent upon guideline product type.

The Medical Technology Assessment Committee is the governing body for the assessment of emerging and evolving technology. This Committee is comprised of

a Medical Technology Assessment Medical Director, the Benefit and Coverage Medical Director, CIGNA Pharmacy, physicians from across the enterprise, the Clinical Resource Unit staff, Legal Department, Operations, and Quality. The Intracorp Guideline Quality Committee is similarly staffed by Senior and Associate Disability Medical Directors.

Revisions are suggested and considered. A vote is taken for acceptance or denial of the CRT.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnostic Confirmation

Subjective Findings

- Fever
- Headache
- Photophobia
- Stiff neck
- Vomiting
- History of antecedent flu-like symptoms

Objective Findings

- NOTE that objective findings are variably sensitive, especially in the pediatric patient
- Bulging fontanelle in infants (indicating increased intracranial pressure)
- Nuchal rigidity is common to both types of meningitis
- Positive (+) Brudzinski's and Kernig sign (occurs more commonly in children older than 18 months)

- A petechial or purpuric rash (often extremely rapid in its evolution) is characteristic of meningocele infection
- Neurological manifestations
- Change in mental status may be the only finding in elderly
- Seizures
- Coma
- Circulatory collapse should suggest bacterial rather than viral meningitis; hemodynamic compromise is a clinical hallmark of meningococcal infection
- Herpangina (painful vesicles at the back of the mouth and pharynx) is a feature of coxsackievirus infection
- Parotitis in the context of meningitis (suggests mumps as an etiology)

Diagnostic Tests

- Lumbar puncture: To prevent possible brain herniation, computerized tomography (CT) scan should be performed before lumbar puncture if any of the following are present:
 - Profoundly depressed mental status
 - Papilledema
 - Focal neurologic deficit
 - Minimal or absent fever
 - History or evidence of head trauma, recent or remote
 - Recent onset of seizure
- Blood cultures
- White blood cell (WBC) count
- Blood urea nitrogen (BUN) and creatinine

Common lab results in bacterial meningitis

- Cerebral spinal fluid (CSF) leukocytosis of between 1,000 to 100,000 WBC/mL, the average being approximately 5,000/mL
- Neutrophils typically predominate, in patients with relatively low WBC counts (less than 1,000/mL) and in cases of partially treated bacterial meningitis
- Lymphocytes may predominate
- Glucose is typically low (less than 50 mg/dL, or below 40% of concomitant blood glucose levels)
- Protein is elevated (greater than 45 mg/dL)
- CSF pressure is nearly always elevated (greater than 180 mm of H₂O)
- Gram stain of the CSF may be an extremely helpful diagnostic aid. CSF cultures may provide the diagnosis

Common lab results in viral meningitis

- Typically CSF contains only 10 to 100 WBCs/mL.
- Leukocytes and mononuclear cells usually predominate
- CSF glucose is generally normal
- CSF protein may be normal or slightly elevated
- Gram stains and cultures are negative
- In patients with few white blood cells, lymphocytic or mononuclear cell predominance, normal protein, and low glucose, fungal or mycobacterial meningitis should be considered

Differential Diagnosis

- Noninfectious meningitis (e.g., malignancy, vasculitis)
- Encephalitis
- Migraine headache (see the Intracorp guideline Migraine)
- Stroke (see the Intracorp guideline Cerebral Thrombosis)
- Epidural or subdural hematoma (see the Intracorp guideline Traumatic Brain Injury)
- Temporal arteritis
- Acute infections with several viruses (e.g., influenzae, Epstein-Barr virus (EBV), human immunodeficiency virus (HIV), hepatitis B, etc.)
- Numerous rickettsial diseases (e.g., Lyme disease, babesiosis, etc.) (see the Intracorp guideline Lyme Disease)
- Fungal central nervous system (CNS) infections
- Tertiary syphilis
- Sarcoidosis
- Toxic or metabolic encephalopathies

Treatment Options

Bacterial meningitis

- Active airway management with endotracheal intubation if required
- Prompt treatment with intravenous antibiotics
- Dexamethasone may be administered if cerebral edema is present
- Intravenous hydration and analgesics

Viral meningitis

- Treatment is aimed primarily at symptomatic relief; however, if the clinical presentation is suspicious for bacterial meningitis, initial treatment with antibiotics is usually indicated.
- The use of antiviral agents is not necessary in uncomplicated cases; in the
 absence of treatment, fever and headache typically resolve within 3 to 5
 days; acyclovir may be used to shorten the course of infection with Varicella
 zoster and Herpes simplex viruses.

Duration of Medical Treatment

- Medical Optimal: 21 day(s), Maximal: 42 day(s)
 - One week post hospital release

Additional information regarding primary care visit schedules, referral options, and specialty care is provided in the original guideline document.

The original guideline document also provides a list of red flags that may affect disability duration, and return to work goals, including

- Viral meningitis with resolved fever
- After hospitalization for bacterial meningitis

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS.

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis, treatment, prevention and management of meningitis that assist medical management leaders to make appropriate benefit coverage determinations

POTENTIAL HARMS

Not stated

CONTRAINDICATIONS

CONTRAINDICATIONS

Menactra vaccine is contraindicated in persons with known hypersensitivity to any component of the vaccine or to latex, which is used in the vial stopper.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005

GUIDELINE DEVELOPER(S)

Intracorp - Public For Profit Organization

SOURCE(S) OF FUNDING

Intracorp

GUIDELINE COMMITTEE

CIGNA Clinical Resources Unit (CRU)
Intracorp Disability Clinical Advisory Team (DCAT)
Medical Technology Assessment Committee (MTAC)
Intracorp Guideline Quality Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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Reprints of complete guideline content may be purchased for \$35.00 per title (plus tax in TX at 8.25% and CT at 1.0%). Please send e-mail request to lbowman@mail.intracorp.com.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Policies and procedures. Medical Technology Assessment Committee Review Process. Philadelphia (PA): Intracorp; 2004. 4 p.
- Online guideline user trial. Register for Claims Toolbox access at www.intracorp.com.

Licensing information and pricing: Available from Intracorp, 1601 Chestnut Street, TL-09C, Philadelphia, PA 19192; e-mail: lbowman@mail.intracorp.com.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on Aug 19, 2005. The information was verified by the guideline developer on September 2, 2005. This summary was updated by ECRI on October 5, 2005 following the U.S. Food and Drug Administration (FDA) advisory on Menactra (Meningococcal Conjugate Vaccine A, C, Y, and W135).

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Date Modified: 9/25/2006